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February 25, 2004

Division of Dockets Management
HFA-305
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. 2003N-0496 --- Advanced Notice
of Proposed Rulemaking: Food Labeling: Health
Claims; Dietary Guidance

Dear Sir or Madam:

The Juice Products Association ("JPA") submits these comments in response to the November 25, 2003, Federal Register notice of the above-referenced Advanced Notice of Proposed Rulemaking (68 Fed. Reg. 66,040 (Nov. 25, 2003)) (the "ANPRM"). JPA is the trade association for the juice and juice products industry. Its international membership includes major processors, packers, and distributors of a wide variety of fruit and vegetable juices, juice beverages, and other juice products located throughout the United States and abroad. JPA represents the great majority of the juice product processors in the United States.

JPA appreciates the opportunity to comment on the thoughtful discussion of FDA's interests and the questions posed in this ANPRM. Because of the frequency with which juice products are consumed and the wide variety of these products available, we believe our product category has been and will continue to be a major contributor to a healthy diet for consumers. Technology, particularly in the food-processing arena, is advancing very rapidly. A regulatory framework for health claims that is built on sound science yet flexible enough to accommodate labeling creativity will go a long way toward stimulating the growth of healthy products in the juice products sector and likely in the

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food industry in general. Our comments that follow address this flexibility but also endorse the need for sound science to prohibit misleading health claims.

Of The Three Options For Qualified Health Claims Outlined In The ANPRM, The Efficiency and Flexibility of Option 1 Make it The Best Approach

In the ANPRM, FDA solicits comments on which of three approaches to qualified health claims the agency should adopt. Option 1 is a type of pre-market notification system under which anyone could petition FDA to permit a qualified health claim and, after a public comment period, FDA would issue a letter in which it would indicate whether it intends to exercise its enforcement discretion to allow the claim. Option 2 would require all qualified health claims to be approved by FDA via notice-and-comment rulemaking. Under Option 3, FDA would regulate qualified health claims only on a post-marketing basis. FDA would only be able to take action against a claim when it determined that it was false or misleading.

JPA favors Option 1 for regulating qualified health claims. It is efficient, transparent, timely, and assures no qualified health claim could be used, under any circumstances, prior to FDA review and the agency's determination that it has no objections. JPA is opposed to Option 2 because of the lengthy process involved. In this case regulatory review policy will never catch up with science and food technology. JPA is strongly opposed to Option 3, the post-market review, because it could easily lead to a proliferation of misleading information undermining consumer confidence in all label claims including health claims. Because qualified health claims under Option 1 would have to be tacitly "approved" by FDA before being used on food labels, this approach would not result in a proliferation of misleading information on labels that could result if Option 3 is pursued. Opening the door to such misleading claims, in Option 3, could seriously undermine the credibility of all health claims.

With respect to its endorsement of Option 1, JPA recommends that this option additionally include a streamlined process for considering the amendment of a qualified

health claim to make it a an unqualified SSA health claim (i.e., meeting the “significant scientific agreement” standard), a claim that is specifically authorized by FDA. Likewise, when an SSA health claim petition is denied by FDA, the petitioner should be permitted to seek “approval” of the claim as a qualified health claim without submitting additional data. However, persons should be strongly encouraged to request only a qualified health claim when there is credible scientific evidence but not significant scientific agreement.

There Should Be Flexibility For The Qualifying Language In A Qualified Health Claim

In its guidance document, “Interim Procedures for Qualified Health Claims in the Labeling of Conventional Human Food and Human Dietary Supplements” (July 10, 2003), FDA specified the exact qualifying language to be used in a qualified health claim depending on the level of scientific support for the claim. The language specified is as follows:

Standardized Qualifying Language for Qualified Health Claims.

Scientific Ranking	FDA Category	Appropriate Qualifying Language
Second Level	B	... "although there is scientific evidence supporting the claim, the evidence is not conclusive."
Third Level	C	"Some scientific evidence suggests ... however, FDA has determined that this evidence is limited and not conclusive."
Fourth Level	D	"Very limited and preliminary scientific research suggests... FDA concludes that there is little scientific evidence supporting this claim."

FDA did clarify in this guidance that: “During this interim period, the precise language as to which the agency considers exercising enforcement discretion may vary depending on the specific circumstances of each case.” Because of the countless “circumstances” that will be presented by each individual claim, it is not sensible to apply a cookie-cutter approach to qualifying language. Before the scientific evidence supporting a particular claim is evaluated, it is not possible to know what language will best convey the strength of the scientific evidence to consumers.

Additionally, JPA believes the discrete linkage of the evidence-based ranking of these claims with the associated specified language will serve to falsely communicate the level of quality and even safety of the products on which the claim appears, not just the strength of the health claim. The qualifying language proposed particularly for C and D claims is so negative, it is difficult to imagine any conventional food manufacturer being willing to associate such a claim with its brands. Semantic nuances are one of the ways food manufacturers differentiate their product in labeling, advertising and promotion. To not allow for creativity in wording a qualified health claim, within the bounds of objective interpretation of sound science, is to foreclose a manufacturer’s First Amendments rights. The opportunity to tailor the wording of the claim to the weight of evidence across a continuum will promote innovation for better health by allowing manufacturers to creatively promote their products.

JPA appreciates the desire by some to have safe harbor wording related to specific categories of scientific evidence. We see nothing wrong with the agency providing examples in any guidance or regulation in this regard. However, we believe that each claim should be evaluated on its own merits, and the wording of that claim should be based upon the evidence to support it.

Last year, in its first application of interim policy for qualified health claims on conventional foods, FDA found there was sufficient evidence to support qualified health claims for walnuts and other tree nuts. The agency agreed that the language of these

claims, which is considerably different than that specified in the above-referenced FDA guidance document, was truthful and not misleading.

From the outset, the person requesting the claim will have the greatest understanding of the nature of the scientific evidence supporting a qualified health claim and, thus, would be in the best position to develop qualifying language accurately describing the level of that support. In almost all other FDA contexts, *e.g.*, petitions for SSA health claims, drug and medical device marketing applications, industry proposes a claim for the agency's consideration, and the agency is free to accept, reject or modify the claim as it deems appropriate. There is no reason why qualified health claims should be treated differently. Therefore, FDA's willingness to vary the "precise language" used during the interim period should be made a permanent part of FDA's regulation of qualified health claims.

The Timeframe For Reviewing A Petition Should Be Well Defined Under FDA's Interim Procedures For Qualified Health Claims.

In the "Guidance for Industry and FDA: Interim Procedures for Qualified Health Claims in the Labeling of Conventional Human Food and Human Dietary Supplements, as referenced in the ANPRM, under Option 1, FDA has outlined a 270-day process, with the possibility of extensions totaling another 60 days, for pre-market notification and review of a qualified health claim. JPA believes that time frame can be shortened. FDA has established much shorter review times for other types of pre-market notifications. In the medical device field, FDA typically reviews pre-market notifications in 90 days. For food packaging materials, if FDA does not act on a Food Contact Notification within 120 days, the submitter can market the substance. JPA believes that the appropriate evaluation for qualified health claims can reasonably be completed within a 180-day period from the time FDA publishes a notice of filing in the Federal Register to completion of review. However, in those circumstances where additional time may be needed for FDA to seek clarification from a notifier, JPA would support two extensions

of 30-days each. JPA believes that FDA should further clarify what will take place during that 180-day period, including interim deadlines.

We propose the following:

- (1) Within 30 days of receipt of notification, FDA would inform the notifier of the date of notification filing. Assuming the notification meets the requisite technical requirements, FDA would publish a notice of filing in the Federal Register including all of the contents of the notification. If the notification is deficient in some respect, within 30 days, FDA would so inform the notifier. There would be an option for re-submission, after curing the noted deficiencies, at which time the 30-day clock would start anew.
- (2) As part of the Federal Register notice of filing, FDA would set forth a 60-day period for public comment inviting all interested parties to submit any data, information or views pertinent to the notification.
- (3) Following the expiration of the 60-day comment period, FDA would have the balance of 180 days from receipt of notification within which to inform, in writing, the notifier that the agency (a) does not object to the proposed claim, (b) objects to the proposed claim or (c) objects to the proposed claim, but would not necessarily object to a revised claim. In the latter case, this would open the door for further discussion between the notifier and FDA concerning the evidence presented and/or the language proposed. JPA believes the opportunity for informal discussion between FDA and the notifier offers an efficient and productive mechanism to achieve qualified health claims that are scientifically-supportable, yet provide flexibility in wording.
- (4) For valid reasons, such as an FDA request for clarification of data submitted, the possibility of two 30-day extensions of time for a final determination may be appropriate.

JPA offers comment on additional questions posed in the ANPRM as follows:

Revised Claim Language for Unqualified Health Claims

The ANPRM requests comment on whether FDA should follow the recommendation of the Task Force on Consumer Health Information for Better Nutrition to remove the requirement for the word “may” from unqualified health claims. This is a difficult question, the answer to which should be largely based on wording of the claim and the weight of the scientific evidence supporting it. The presence of the word “risk” in a health claim may provide enough qualification for the cause and effect relationship between the stated nutrient or other ingredient and the referenced health condition or disease. As FDA points out in the ANPRM, the etiology of many health conditions and diseases are multi-factorial. However, the use of the term “risk” is a relative term that conveys to consumers that consumption of the product labeled with the health claim will not necessarily prevent the health condition or disease, but will reduce the likelihood of that outcome.

On the other hand, if the weight of evidence supporting the health claim is only strong enough to support a conditional claim, e.g., “as part of diet low in saturated fat”, then use of the word “may” is likely appropriate. JPA believes FDA should have the latitude to make this determination when considering the evidence supporting the health claim and the language that is determined to best reflect the weight of evidence supporting the claim.

Interim Final Rules for Unqualified Health Claims

Noting that “as a general matter [historically], comments have not persuaded the agency that any particular proposed health claim should not be allowed”, the ANPRM asks whether FDA should continue to use the Interim Final Rule process for some or all unqualified health claims. As technology continues to advance and scientific research continues to reveal relationships between nutrients and/or ingredients in food with favorable health outcomes, consumers should have the benefit of this knowledge as soon as it is justifiable. In the case of plant sterol/stanol esters and the reduced risk of

coronary heart disease, FDA apparently felt the evidence it reviewed to be so compelling that it determined consumers would benefit from these ingredients in food as soon as possible. It is very likely that manufacturers would not have gone to the expense of adding this ingredient had they not been permitted to tell the consumer, via the product label, why the ingredient had been added. JPA believes when the evidence is strong enough to support an unqualified health claim, the IFR process is of significant benefit to consumers.

Use of Phrases Such as “FDA authorized” in Qualified and Unqualified Health Claims.

JPA notes that there have been too many instances where unscrupulous parties without authorization have used phrases, such as “FDA approved” to communicate FDA endorsement. This triggers FDA enforcement activity using considerable resources. If FDA follows the process outlined in JPA’s version of Option 1, every qualified health claim will be understood to have been reviewed by FDA and to carry FDA’s tacit approval. JPA believes that the opportunity for misuse of the government equivalent of the Good Housekeeping Seal of Approval is great and therefore recommends against the use of such a statement.

Consumer Education

In the ANPRM, FDA requests comments on the how the agency could best educate consumers about the role of qualified health claims on food labels. The qualification of a health claim, in and of itself, is a means of educating consumers about the relative health benefit of particular nutrient and/or ingredient. The resources the agency would require to effectively communicate to consumers the differences between SSA claims and qualified health claims, with respect to the evaluation of science, would significantly challenge FDA’s budget. Furthermore, we question how relevant this distinction is to consumer understanding of health claims. The wording of the claim, not some complicated distinction between SSA claims and qualified claims, is the critical element relative to consumer understanding and favorably changing consumer behavior.

Evaluations of Outside Scientific Groups

FDA is requesting comment on whether the evaluations of non-governmental groups should be given weight in evaluating the strength of the science supporting a health claim. JPA responds with a qualified yes. The objective interpretation of sound science is not necessarily dependent on the source of that interpretation. Many of the same individuals who do scientific assessment for organizations such as the American Heart Association or the American Dietetic Association are the very same individuals appointed to serve on government scientific advisory committees. It should be the job of FDA reviewers to determine the weight and strength of evidence and the objectivity of its interpretation based on criteria for scientific assessment, not the source of the information.

However, we qualify this position by strongly emphasizing that when FDA relies upon data from any scientific source, government or otherwise, it should take note of how that information was presented and not take the information out of context to support a pre-determined position. For example, in its “Interim Evidence-based Ranking System for Scientific Data” guidance, FDA points out that the agency tentatively chose to model its evidence-based rating system based on that of the Institute for Clinical Systems Improvement as adapted by the American Dietetic Association (ADA). We question whether ADA had qualified health claims in mind, specifically with respect to discrete categories rather than a continuum of evidence to support such claims, when adapting this system.

Competent and Reliable Evidence

FDA seeks comment on how it should interpret the term “credible evidence” in the context of qualified health claims. The ANPRM notes that “the FTC [Federal Trade Commission] defines ‘competent and reliable scientific evidence’ as ‘tests, analyses, research studies or other evidence’ based upon the expertise of professionals in the relevant area, that has been ‘conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate

and reliable results’.” JPA believes the FTC definition of “competent and reliable evidence” generally can be applied to the term “credible evidence”. However, the phrase, “generally accepted” in the FTC definition, like the phrase, “significant scientific agreement” typically describes procedures that have survived the test of time and general use. This could eliminate the application of new procedures that have not yet been widely used, but that could measure up to the rigor and validity of more well-established procedures.

We also recommend that FDA consider the requirement that “credible evidence” specifically include a written protocol that adequately describes the research, evidence of the informed consent of the test subjects in all human studies, a statistical analysis of the research results and a written report of the research including its conclusions. We again emphasize that the specific type and quantity of credible evidence required to support a qualified health claim is dependent on how the claim is worded.

Issues Related to Dietary Guidance

The ANPRM goes to great lengths to differentiate dietary guidance from health claims. It bases this differentiation on whether a class of foods or a substance is related to a health condition or a disease. A class of foods (e.g., fruits and vegetable, whole grains) is the marker for dietary guidance, while a substance (e.g., calcium) is associated with a health claim. JPA is comfortable with this distinction and believes that dietary guidance statements should “focus on general dietary patterns, practices, and recommendations that promote health” as is stated in the ANPRM.

JPA believes that dietary guidance statements such as “Diets rich in fruits and vegetables may reduce the risk of some types of cancer and other chronic diseases” are very meaningful to consumers particularly when they originate from such trusted sources as the National Cancer Institute. Their use, where appropriate, on food labels will assist in fostering good nutrition behavior among consumers. While these statements are valuable, we do not necessarily agree that it should be FDA’s role to be the gatekeeper for dietary guidance statements.

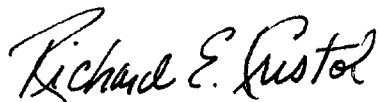
FDA requested comments on “substitutions” or “replacements” in dietary guidance. These questions are largely related to nutrient substitution in the context of a healthy diet (e.g., substitute mono- and polyunsaturated fat for saturated fat to promote heart health). JPA is in favor of giving consumers this type of guidance, which certainly can help consumers eat a healthier diet, as long as it is based on sound science. However, in the context of qualified health claims, FDA should look at any comparative claims with heightened scrutiny, as it did with the folic acid qualified health claim. That claim compares the efficacy of folic acid in dietary supplements to folic acid in conventional foods at reducing the risk of neural tube defects. While they may be based on sound science, comparative claims can raise competition issues and, therefore, a heightened degree of scrutiny may be warranted and the views of “both sides” of the claim should be carefully evaluated.

Final Thought

JPA would like to add that it is important to those who comply with existing and future regulations that FDA vigorously exercise its enforcement authority against misleading health claims. To do so will not only assure FDA’s continuing credibility with consumers and manufacturers, but will also maintain consumer confidence in the information provided on food labels.

The Juice Products Association appreciates this opportunity to comment on this Advance Notice of Proposed Rulemaking.

Sincerely,

A handwritten signature in black ink that reads "Richard E. Cristol". The signature is written in a cursive, flowing style.

Richard E. Cristol
President